

**REMARKS****I. Status of the Claims**

With this amendment, claims 1-40, and 43-53 are pending in the present application and are under examination. Claim 1 has been amended. Claims 52 and 53 have been added as new claims. In the Office Action dated January 23, 2009, claims 1-40 and 43-47 were rejected, claims 48-51 were allowed.

**II. Claim Rejections 35 USC 112, 1st paragraph**

Claims 1-40 and 43-47 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such way as to reasonably convey one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse the rejection and its supporting remarks. However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, and applicants expressly reserve the right to pursue claims of the same scope in one or more continuations. As amended, the claims no longer recite "an HIV Pol polypeptide." One of skill in the art would clearly understand that the inventors were in possession of the currently claimed subject matter.

Applicants thus respectfully request that the rejection under 35 U.S.C. 112, first paragraph, be withdrawn with respect to claims 1-40 and 43-47.

**III. Double Patenting 35 USC 101**

Claims 1, 5-11, and 19-21 are rejected under 35 U.S.C. 101 as allegedly claiming the same invention as claims 1, 16-22, and 30-32 of U.S. Patent No. 7,211,659 (Application No. 10/190,435). The Examiner alleges that the polynucleotide sequence SEQ ID NO: 9 in the claims of '659 has at

least 90% sequence identity to SEQ ID NO: 30-32 in the instant claims (99.2% sequence identity with SEQ ID NO: 32 in the instant claims).

Applicants respectfully traverse the rejection and its supporting remarks. A rejection for statutory double patenting is only proper when the claims for the two patents or applications are for the same invention, one test for which is to ask whether a claim in a patent can be literally infringed without infringing the claims in the application and vice versa. See § MPEP 804(II)(A). If one claim can be literally infringed without infringing the other claim, then they do not claim the same invention. Applicants respectfully assert that under this test, the rejection of the presently pending claims is invalid.

The presently pending claims are all directed to SEQ ID NOs: 30-32, which generally encompass sequences encoding the following HIV polypeptides: p2, p7, p1/p6, protease, reverse transcriptase, 6 amino acids of integrase as shown in Figure 7, followed by a multiple cloning site and a YMDD epitope cassette. SEQ ID NO: 9 from U.S. Patent No. 7,211,659 generally encompasses sequences encoding the following HIV polypeptides: *p17gag*, *p24gag*, p2, p7, p1/p6, a repeat of p2, p7, p1/p6, protease, reverse transcriptase, 6 amino acids of integrase, followed by a multiple cloning site and a YMDD epitope cassette.

Thus, instant claim 1 is directed to polynucleotides encoding an HIV-1 subtype C Protease-Reverse-Transcriptase polypeptide (SEQ ID NOs: 30-32). In contrast, claim 1 in the cited patent is directed to a polynucleotide encoding an HIV-1 subtype C *Gag*-Protease-Reverse-Transcriptase polypeptide (SEQ ID NO: 9). The sequence of SEQ ID NO: 9 is clearly distinct from the sequences in the presently pending claims (SEQ ID NOs: 30-32) as it includes Gag coding sequence. This is further confirmed by performing a local sequence alignment using BLAST between SEQ ID NO: 9 and SEQ ID NO: 32 resulting in 70% identity and not 99.2% sequence identity, as suggested by the Examiner in the Office Action from January 23, 2009. Applicants assume that the Examiner aligned the two sequences using SEQ ID NO: 32, the shorter sequence, as the reference sequence. Thus, the additional part of SEQ ID NO: 9 encoding Gag was ignored as extra overhang by the sequence alignment program. However, this is not the correct analysis in determining the scope of

claim 1 in the issued patent. SEQ ID NO: 9 must be used as the reference sequence to determine if a vector with SEQ ID NO: 32 (as included within the scope of the instant claim 1) would infringe. As indicated, since SEQ ID NO: 32 lacks Gag, it has only 70% identity to SEQ ID NO: 9 when SEQ ID NO: 9 is used as the reference sequence.

Thus, a sequence only including, for example, SEQ ID NO: 32 with no additional sequence encoding the Gag polypeptide would not infringe the patented claims, but would infringe the pending claims. Therefore, under the test cited in the MPEP, the patented claims and claims in this application are not to the same invention.

Applicants thus respectfully request that the statutory double patenting rejection be withdrawn with respect to claims 1, 5-11, and 19-21.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 223002109720. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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